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MAR 1 2 2004

510(k) Summary

Name of Sponsor:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact:

Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs

Phone: (574) 371-4905
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Email: Dweissma@dpyus.jnj.com

Trade Name:

Spectrum Modular System

Common Name:

Femoral Hip Joint Uncemented Prosthesis

Classification:

Class II device per 21 CFR 888.3358:
Hip joint metal/polymer semi-constrained uncemented prosthesis

Device Product Code:

87LPH Hip joint metal/polymer semi-constrained uncemented prosthesis

No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

Substantially Equivalent Devices:

Titan Porocoat Hip Prosthesis	K001991
Malory Head Modular Calcar	K001660
ZMR Hip System Revision Taper	K992667
Link Mp Reconstruction Hip	K955296

Device Descriptions:

The Spectrum Modular System is a three-piece, uncemented femoral hip prosthesis consisting of a proximal body, a distal stem and a locking nut. The proximal bodies and distal stems are interchangeable, allowing each to be independently positioned. They are available in a variety of proximal body lengths, distal body diameters and lengths. The system is manufactured from titanium alloy.

510(k) Summary (continued)

Indications for use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Substantial equivalence:

The Spectrum Modular System uncemented femoral hip prosthesis has the same intended use and basic design as the predicate devices and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Ms. Diana L. Weissman, J.D.
Depuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedics Drive
Warsaw, Indiana 46581-0988

Re: K033893
Trade/Device Name: Spectrum Modular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: December 15, 2003
Received: December 16, 2003

Dear Ms. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

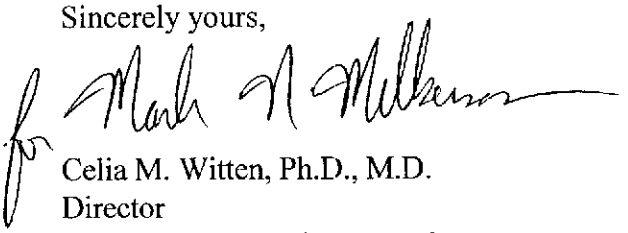
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033893

Device Name: Spectrum Modular System

Indications for Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

This device is intended for single use.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use No

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033893